UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FOOD & WATER WATCH, INC., 1616 P Street NW Suite 300 Washington, DC 20036, *Plaintiff,* v. U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, *Defendant.*	§	Civil Action No._____

COMPLAINT FOR DECLARATIVE AND INJUNCTIVE RELIEF

I.

Introduction

1. Plaintiff, Food & Water Watch, Inc. ("FWW"), brings this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 (2006). Through a FOIA request, FWW and the Johns Hopkins Center for a Livable Future ("CLF") have sought U.S. Food and Drug Administration ("FDA") records related to the agency's communications with pharmaceutical companies related to the use, approval, effects, sale, safety, or withdrawal of any product that contains arsenic compounds (or "arsenicals") and is intended to be used as an animal drug. The Defendant has violated FOIA by failing to respond to the request within the statutorily prescribed time limit and is unlawfully withholding the requested information. FWW now asks the Court to

enjoin the Defendant to respond to the request and produce all responsive agency records improperly withheld from the Plaintiff.

II.

Jurisdiction and Venue

2. The Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B) (2006) and 28 U.S.C. § 1331 (2006). Venue is proper under 5 U.S.C. § 552(a)(4)(B) (2006).

III.

Parties

3. Based in Washington, DC, Plaintiff FWW is a national, non-profit, public interest, consumer advocacy organization that works to ensure safe food and clean water. FWW has long advocated against the use of arsenical drugs in animal feeds.

4. Defendant FDA is an agency of the United States, within the meaning of 5 U.S.C. § 552(f) (2006). It has possession of, and control over, the records that FWW and CLF seek.

IV.

General Allegations

A. Background on the subject of FWW's FOIA requests, communications related to arsenical-based animal feed drugs

5. FDA has approved arsenical drugs for use in chickens, turkeys, and pigs. These drugs are approved for multiple purposes, including growth promotion, improved pigmentation, and to treat, control, and prevent animal diseases, such as coccidiosis, a parasitic infection of the intestinal track in poultry. The most common arsenical drug is roxarsone (commonly marketed as "3-Nitro"), which FDA first approved in 1944. Over one hundred arsenical "combination drugs" have been approved since this time.

6. As chicken operations grew larger from the 1950s onward, the use of roxarsone became a standard practice. In 2010, industry representatives estimated that 88 percent of the approximately 9 billion chickens produced annually in the United States for human consumption received roxarsone in their feed.

7. The use of arsenical drugs in food animal production has created a number of public health concerns. These include concerns related to exposure to increased levels of inorganic arsenic when people consume chicken produced with arsenical drugs and increased environmental exposure to inorganic arsenic from chicken waste that is applied to agricultural cropland or is incinerated.

8. Chronic exposure to inorganic arsenic causes bladder, lung, and skin cancers. Inorganic arsenic exposure may also lead to cardiovascular disease and diabetes, neurological problems in children, and adverse pregnancy outcomes.

9. The arsenic compounds contained in arsenical drugs are organic, meaning that the compounds contain carbon as well as arsenic. The human toxicity of organic arsenic is less clear than the toxicity of inorganic arsenic. There is evidence that the organic arsenic contained in arsenical drugs is converted into toxic inorganic arsenic in chickens that receive these drugs.

10. On June 8, 2011, FDA announced the results of a study conducted by the agency that associated the use of roxarsone in chickens with increased concentrations of inorganic arsenic in the livers of chickens that received these drugs.

11. On the same day that FDA announced these results, the company that sold roxarsone (Alpharma, a subsidiary of Pfizer, Inc.) announced that it would voluntarily suspend sale of roxarsone in the United States as of July 8, 2011.

12. Despite FDA's study results and the resulting suspension of sale, a press release by the agency issued on this same date stated that "continuing to eat chicken as 3-Nitro is suspended from the market does not pose a health risk."

13. FDA did not withdraw any arsenical drug approvals in response to its study.

14. More recently, a study led by CLF scientists, published in the peer-reviewed journal *Environmental Health Perspectives* (to be available online on May 10, 2013), found that concentrations of inorganic arsenic in the breast meat of conventionally produced chickens (*i.e.*, chickens that by law may receive arsenical drugs, including roxarsone) were approximately three times greater than the concentrations of inorganic arsenic in breast meat from USDA certified organic chickens, which by law may not receive arsenical drugs. The chicken analyzed in the study was purchased between December 2010 and June 2011, before sale of roxarsone was suspended.

15. Despite strong evidence of a public health risk and the voluntary suspension of roxarsone sales, FDA's approvals of more than one hundred arsenical drugs remain in effect. Drugs that contain an arsenical active ingredient known as nitarsone, which has a chemical structure that is similar to roxarsone, are still sold in the United States. Arsenical drugs may be sold overseas as well.

B. Plaintiffs' FOIA Request

16. On August 21, 2012, FWW and CLF submitted a FOIA request seeking

> Any and all communications, including emails, letters, notes, reports and other documents, from January 2008 to date, between FDA and any and all drug manufacturing companies, including, but not limited to, Pfizer Inc. and its subsidiaries including Alpharma LLC; Elanco Animal Health; Intervet, Inc.; Phibro Animal Health, Inc.; and Merial Ltd. regarding the use, approval, effects, sale, safety or withdrawal of any product that contains arsenicals and is intended to be used as an animal drug. Our reference to arsenicals includes any arsenic compound, including, but not limited to, 3-Nitro® (also known as "roxarsone" or

"roxarsone granules"), arsanilic acid, nitarsone and carbasone.

17. FWW and CLF wish to analyze and evaluate how FDA is fulfilling its obligation to oversee the use of arsenical drugs in animal feeds and attempt to reconcile the agency's claims regarding the health risks posed by these drugs with both scientific studies that contradict these claims and the announced suspension of roxarsone drug sales.

18. On August 23, 2012, FDA sent an email to FWW indicating that it received the FOIA request, and assigning it a reference number of 2012-6158. The email indicates that the agency would respond to the request as soon as possible.

19. Over the course of the next eight months, FWW staff attempted to follow up with FDA on numerous occasions via phone and voicemail.

20. While FDA has responded to a few of FWW's emails and calls and left one voicemail, the Defendant has yet to issue a response to FWW and CLF's request.

21. FDA has never asked FWW or CLF that the deadlines for its response be tolled or indicated that it could not respond to the request in a timely manner due to unusual circumstances.

V.

First Claim for Relief

Defendant Has Violated FOIA by Failing to Respond to FWW and CLF's Request.

22. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs 1-21 in the complaint as if fully set forth herein.

23. Under FOIA, "[e]ach agency, upon any request for records . . . shall. . . determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any

such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination[.]" 5 U.S.C. § 552(a)(6)(A) (2006).

24. The FDA was required to respond to FWW and CLF's request no later than September 12, 2012.

25. FDA has never notified FWW and CLF of its determination regarding their request.

26. Therefore, Defendants have violated FOIA by failing respond to FWW and CLF's request.

27. The Plaintiff has effectively exhausted its administrative remedies under 5 U.S.C. § 552(a)(6)(C)(i) (2006) because FDA has failed to meet the applicable 20-day deadline for providing a response.

VI.

Second Claim for Relief

Defendant Has Violated FOIA by Failing yo Disclose Records Responsive to FWW and CLF's Request.

28. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs 1-27 in the complaint as if fully set forth herein

29. Under FOIA "each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A) (2006).

30. FWW and CLF's request reasonably described the agency records it sought and was made in accordance with FDA's rules and procedures.

31. The Defendant has effectively denied the request by failing to provide all responsive documents.

32. The Plaintiff effectively exhausted its administrative remedies under 5 U.S.C. § 552 (a)(6)(C)(i) because FDA has failed to meet the applicable 20-day deadline for providing a response.

33. There is no legal justification for Defendant to withhold the requested records.

34. Therefore, Defendant has violated FOIA by failing to disclose the requested records to the Plaintiff.

VII.

Relief Requested

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Declare as unlawful Defendant's failure to respond to Plaintiff's August 21, 2012 FOIA request;

B. Declare as unlawful Defendant's failure to disclose the records that Plaintiff requested on August 21, 2012;

C. Order Defendant to expeditiously provide all the records requested by Plaintiff;

D. Exercise close supervision over Defendants while they process Plaintiff's request;

E. Award Plaintiff his costs and reasonable attorney's fees pursuant to 5 U.S.C. § 552(a)(4)(E); and

F. Award any other relief that the Court deems just and proper.

Respectfully submitted,

/s/

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Dated: May 10, 2013